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Fleit Gibbons Gutman Bongini & Bianco PL			EXAMINER	
21355 EAST DIXIE HIGHWAY			MCEVOY, THOMAS M	
SUITE 115				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,063	Applicant(s) HAZUT ET AL.
	Examiner THOMAS MCEVOY	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 April 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-7, 9, 14-24, 27 and 28 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-7, 9, 14-24, 27 and 28 is/are rejected.
 7) Claim(s) ____ is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/06)
 Paper No(s)/Mail Date 6/3/2010

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date: ____

5) Notice of Informal Patent Application
 6) Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification (specifically paragraph 0029 of the pre-grant publication) does not clearly state that the pad should be removed in a period of time no more than twenty minutes as now required by amended claim 22.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-5, 9, 14-18, 21, 23, 24, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943).

Regarding claims 1, 5 and 9 Malodobry discloses a method for removing pigments from a pigmented section of skin, comprising: a) puncturing the skin at said pigmented section with a skin-puncturing device provided with at least one solid needle, thereby liberating the pigments and cellular fluids from cells containing said pigments (paragraphs 0043-0048). Malodobry fails to disclose b) bandaging said punctured skin with a pad adapted to absorb said pigments and said cellular fluids, said pad containing one or more materials capable of accelerating a process of migration of said pigments toward an outer layer of the skin, wherein said one or more materials is a salt-based granular paste. Malodobry does disclose using irritants such as sodium chloride to increase exudate and thereby increase the amount of pigments migrating towards the outer layer (this is clearly the intent of using irritants as disclosed in paragraphs 0050-0052; Examiner notes that the use of irritants is disclosed immediately after Malodobry discloses an intent to use wound exudate to carry pigments to the skin surface; see paragraph 0049). Bogart et al. disclose bandaging a wound with a pad (col. 9, lines 31-35; col. 3, lines 49-54) containing a sodium chloride based granular (col. 4, lines 42-46) paste (a granular gel can be considered as a paste; Applicant has provided experimental data which disclosed the paste as KY gel and salt) to accelerate a process of skin exudate and bacteria migration to an outer layer of skin (col. 4, lines 60-63; col. 9, lines 44-60). It would have been obvious to one of ordinary skill in the art in view of Bogart et al. to have used a pad and paste as claimed for a number of reasons. For example, Malodobry suggests using a sodium chloride irritant but does not give a specific method for applying it. The device and method of Bogart et al. would provide

one of ordinary skill in the art with a specific device and method for implementing Malodobry's suggestion of using a sodium chloride irritant to increase wound exudate or drainage. One of ordinary skill in the art would also recognize that the device and method of Bogart et al. would especially enable the exudate to carry the pigments as intended by Malodobry because Bogart et al. teach that their method would cause exudate to sweep bacteria to the outer layer and bacteria can be as large or larger than the pigment agglomerates. One of ordinary skill in the art would at least be motivated to apply the method of Bogart et al. to heal the wound of Malodobry after the pigments are substantially removed. The step(s) provided by Bogart et al. could still be considered as part of the overall method of pigment removal. Regarding claims 2 and 15, Bogart et al. further teach applying one or more antiseptic materials to the punctured skin via the paste (col. 6, lines 27-28 and elsewhere). Regarding claim 3, the paste of Bogart et al., containing the antiseptic materials, can be applied with a pad as explained above. Regarding claim 4, the skin-puncturing device of Malodobry is a tattooing device (paragraph 0046). Regarding claims 14 and 18, Malodobry discloses injecting aqueous irritant into the pigmented section as claimed (paragraph 0050). It would have been obvious to one of ordinary skill in the art to have maintained this step when modifying with Bogart et al. because one of ordinary skill in the art would recognize that this step could further help the process of pigment migration in addition to the modification described above. Regarding claim 16, Bogart et al. teach impregnating the pad with the gel (col. 3, lines 49-54) as well as providing antibiotics within the gel as described above. Regarding claim 17, it would have been obvious to one of ordinary skill in the art

to have modified the gel/paste as claimed because 1) both Malodobry and Applicant use the same method for creating the wound which should produce a comparable amount of exudate or drainage within a comparable amount of time and 2) Bogart et al. teach absorbing the exudate into the pad/paste as it comes out of the wound (col. 9, lines 31-40). Regarding claim 21, it would have been obvious to one of ordinary skill in the art to have not provided tattooing ink with the tattooing device in the above method because the method is intended to remove ink already present in the skin. Regarding claim 23, Bogart et al. teach that the pad should be designed to hold exudate away from the wound (col. 9, lines 36-38). Therefore, it would have been obvious to one of ordinary skill in the art to have removed the pad prior to complete saturation in order to prevent excess exudate from leaking out of the pad and on or around the wound. Furthermore, it would have been obvious to one of ordinary skill to remove the pad prior to saturation in order to prevent the pad from leaking fluid onto a patient. Regarding claim 24, Bogart et al. teach securing an absorbent dressing or pad (col. 9, lines 31-34; col. 10, lines 46-49). It is old and well-known in the art that absorbent pads are typically applied by wrapping or securing an absorbent pad to a wound with gauze or medical tape. Therefore, it would have been obvious to one of ordinary skill in the art to have secured an absorbent dressing or pad to the wound using by wrapping or covering the pad with gauze or medical tape. Regarding claim 27, Bogart et al. teach removing the pad after draining a sufficient amount of exudate and then applying a second pad to promote healing as explained above. Bogart et al. also teach applying antibiotics as explained above. It would therefore have been obvious to one of ordinary skill in the art

to have provided antibiotics on the second pad because they would promote healing by reducing the chance of infection. Regarding claim 28, Bogart et al. disclose bandaging the wound with a pad impregnated with the paste (col. 3, lines 43-53; col. 13, lines 4-6).

5. Claims 6, 7, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Garitano et al. (US 2004/0158196).

Regarding claims 6, 7, 19 and 20, Malodobry in view of Bogart et al. disclose the invention as described above. They do not disclose performing the suction of the pigments from said punctured skin with the suction means prior to the bandaging of the punctured skin and during the puncturing of said skin. Garitano teaches the suction of a solution provided for the removal of tattoos (paragraph 0023). Performing this step during the puncturing step would have been obvious to a person having ordinary skill in the art because prior to this step, there is no fluid to be suctioned. Also, performing this step prior to bandaging would have been obvious because after bandaging, the suction step would not be easily performed. Furthermore, the Examiner notes that no specific advantage was provided for the ordering of these steps so it is considered within the purview of one having ordinary skill in the art to rearrange the order of steps (see MPEP 2144.04 IV C). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the Malodobry removal steps to include Garitano's suction step. Such a modification would draw fluid from the tattoo to further aid in the removal of the pigments.

6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Malodobry (US 2004/0111107) in view of Bogart et al. (US 5,271,943) and further in view of Dosch et al. (US 7,012,096 B2).

Regarding claim 22, it would have been obvious to one of ordinary skill to remove the pad before damaging the skin. Bogart et al. disclose using any gelling agent for their invention. Dosch et al. disclose a gelling agent composition suitable for pain mediation of wounds (claim 9) which can be applied for 20 minutes (col. 8, lines 4-11) and other short periods. Therefore, it would have been obvious to one of ordinary skill in the art to have used the gelling agent composition of Dosch et al. with the paste of Bogart et al. in order to sooth pain and to have applied the paste for 20 minutes or less.

Response to Arguments

7. Applicant's arguments, including the 1.132 Declaration, with respect to pending claims have been considered but are not persuasive. Applicant has argued that one of ordinary skill in the art would not combine Malodobry with Bogart et al. because Malodobry intends to delay wound healing and Bogart et al. intend to promote wound healing. Examiner respectfully disagrees. Malodobry only intends to delay wound healing when using fillers that do not produce an irritant effect (paragraph 0051). The main intent of Malodobry is to maximize exudate flow. Irritants are given as one example – they maximize exudate flow rate and/or amount if healing is delayed. Fillers are another – they maximize the amount of flow by delaying wound healing. Malodobry also discloses solely using the natural amount of exudate flow (paragraph 0049),

therefore healing delay is not a primary concern. Bogart et al. "promote" wound healing in several ways. One of which is to eliminate bacteria by flushing and/or destruction (col. 8, lines –11). This component of their attempt to promote wound healing does not speed-up the process and most likely delays it when high salt concentrations are used (col. 9, lines 46-64 - noting that in a subsequent stage a lower salt concentration is substituted to "protect" skin cells). Regardless of whether Bogart et al. speed-up the wound healing process or not, they clearly increase the amount and rate of exudate flow (col. 9, lines 50-60) which is exactly the intent of Malodobry. Applicant has argued that one of ordinary skill in the art would not recognize that the method of Bogart et al. would help to sweep away pigment granules because they are much larger and more massive than bacteria. Examiner believes this is only one reason to combine the references. One of ordinary skill in the art would recognize that the paste or pad of Bogart et al. could be applied to the wound of Malodobry after the pigments are substantially removed (as part of the overall method) in order to heal the wound. However, the prior art indicates that tattoo pigment granules can be comparable in size to bacteria (see attached References Cited). Applicant has argued that the gel of Bogart et al. would lessen upward exudate flow because it penetrates the skin surface and blocks upward flow. Examiner believes that col. 9, lines 50-60 of Bogart et al. refute this. Furthermore, in some embodiments of the Bogart et al. method, the gel does not penetrate the wound (col. 3, lines 43-53; col. 13, lines 4-6).

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas McEvoy whose telephone number is (571)270-5034. The examiner can normally be reached on M-F, 9:00-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas Mcevoy/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
7/17/10